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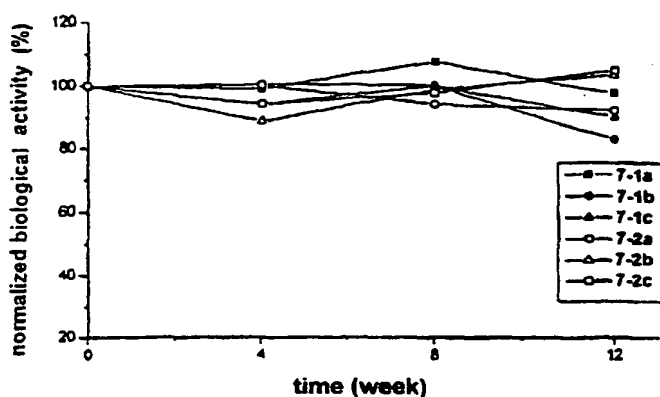
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(54) Title: AN AQUEOUS SOLUTION FORMULATION OF ALPHA-INTERFERON



(57) Abstract: The present invention relates to an aqueous solution formulation which can retain the biological activity and physicochemical properties of α -interferon for a long period. More particularly, the present invention relates to an aqueous solution formulation of α -interferon comprising α -interferon; a stabilizer; an osmotic pressure regulating agent; antimicrobial preservatives selected from the group consisting of phenol, m-cresol or mixture thereof; and a buffer system. The aqueous solution formulation of the present invention has many advantages because it retains the activity of α -interferon for a long period, eliminates potential harmfulness to human body by minimizing the amount of the preservatives, and is very stable.

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What is claimed is;

1. An aqueous solution formulation of α -interferon comprising α -interferon; a stabilizer; an osmotic pressure regulating agent; antimicrobial preservatives
5 selected from the group consisting of phenol, m-cresol or mixture thereof ; and a buffer system.
2. The aqueous solution formulation of α -interferon according to Claim 1, wherein the amount of α -interferon added is in the range of 1×10^6 IU/ml $\sim 1 \times 10^8$ IU/ml.
- 10 3. The aqueous solution formulation of α -interferon according to Claim 1, wherein the stabilizer is polysorbate 80.
4. The aqueous solution formulation of α -interferon according to Claim 3, wherein the concentration of polysorbate 80 is in the range of 0.01 \sim 0.05 w/v %.
- 15 5. The aqueous solution formulation of α -interferon according to Claim 1, wherein the osmotic pressure regulating agent is sodium chloride.
6. The aqueous solution formulation of α -interferon according to Claim 1, wherein the preservative is selected from the group consisting of 0.1 \sim 0.3 w/v % phenol, 0.1 \sim 0.2 w/v % m-cresol, or mixture thereof.
- 20 7. The aqueous solution formulation of α -interferon according to Claim 1, wherein the buffer system is a buffer system consisting of ammonium acetate and acetic acid; or a buffer system consisting of sodium monohydrogen phosphate (Na_2HPO_4) and sodium dihydrogen phosphate (NaH_2PO_4).
8. The aqueous solution formulation of α -interferon according to Claim 7,

wherein the concentration of the buffer system in the aqueous solution formulation is in the range of 5 ~ 20 mM.

9. The aqueous solution formulation of α -interferon according to Claim 1, wherein the pH of the formulation is in the range of 4.5 ~ 6.0.

